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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

HOSPIRA, INC. and ORION
CORPORATION,

Plaintiffs,

v.

SANDOZ INTERNATIONAL GmbH,
SANDOZ INC., and SANDOZ CANADA INC.

Defendants.

Civil Action No. 3:09-cv-04591-MLC-TJB

Filing Date: September 4, 2009
Judge Mary L. Cooper

REDACTED VERSION

**SANDOZ CANADA AND SANDOZ INC.'S MEMORANDUM OF LAW
IN RESPONSE TO PLAINTIFFS' REQUEST TO PRECLUDE
SANDOZ INC.'S AND SANDOZ CANADA INC.'S PROPOSED
INVALIDITY AND NON-INFRINGEMENT CONTENTIONS**

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- “Sandoz Br. at ___”: Memorandum of Law in Support of Sandoz Canada Inc.’s Right to Serve Invalidity and Non-Infringement Contentions and Sandoz Inc.’s Motion for Leave to Amend its Preliminary Invalidity and Non-Infringement Contentions, dated September 10, 2010.
- “Pls. Br. at ___”: Plaintiffs’ Brief in Support of their Request to Preclude Sandoz Inc.’s and Sandoz Canada’s Proposed Invalidity and Non-Infringement Contentions, dated September 10, 2010.
- “Ex. ___”: Exhibits to the Declaration of Kyle Mooney in Support of Sandoz Canada Inc.’s Right to Serve Invalidity and Non-Infringement Contentions and Sandoz Inc.’s Motion for Leave to Amend its Preliminary Invalidity and Non-Infringement Contentions, dated September 10, 2010.
- “Antonian Ex. ___”: Exhibits to the Confidential Certification of Agnes Antonian, dated September 10, 2010.
- “9/22 Mooney Ex. ___”: Exhibits to the Declaration of Kyle Mooney in Further Support of Sandoz Canada Inc.’s Right to Serve Invalidity and Non-Infringement Contentions and Sandoz Inc.’s Motion for Leave to Amend its Preliminary Invalidity and Non-Infringement Contentions, dated September 22, 2010.

Defendants Sandoz Canada Inc. ("Sandoz Canada") and Sandoz Inc. respectfully submit this memorandum in response to Plaintiffs' request to preclude Sandoz Inc.'s and Sandoz Canada Inc.'s proposed invalidity and non-infringement contentions. Sandoz Canada Inc. and Sandoz Inc. (collectively, "Defendants") respectfully submit that Plaintiffs' request should be denied, that Sandoz Canada should be entitled to serve invalidity and non-infringement contentions (and be served with infringement contentions), and that Sandoz Inc. should be granted leave to amend its invalidity and non-infringement contentions.

PRELIMINARY STATEMENT

In their opening brief, Plaintiffs identify no authority for the proposition that a new party to the case, Sandoz Canada, should be precluded from serving invalidity and non-infringement contentions under the Local Patent Rules for the District Court of New Jersey. Plaintiffs likewise identify no unfair prejudice that arises from Sandoz Inc.'s proposed amendments, which derive primarily from information or documents from Plaintiffs' own files, witnesses, or sponsored tests. Rather, Plaintiffs' opposition derives from one simple concern: the prior art and documents confirm that the Patents-In-Suit are anticipated and/or obvious and that Plaintiffs' representations to the PTO to overcome obviousness rejections were baseless. Plaintiffs' effort to avoid litigating the merits of this case, however, suffers from three fundamental flaws.

First, as to Sandoz Canada, Plaintiffs cannot escape the fact that they chose to sue Sandoz Canada more than eight months after this litigation began, and that this decision has substantive and procedural consequences. For its part, Sandoz Canada will be bound by the outcome of this litigation, win or lose. But having now joined Sandoz Canada as a party, and obtained the associated potential benefits and security, Plaintiffs must also accept the consequences—including Sandoz Canada's fundamental due process right to set forth its contentions based on its present knowledge, and to receive contentions from Plaintiffs specifically describing its alleged

infringement. That Sandoz Canada was [REDACTED] does not change its legal rights in this litigation. Plaintiffs' argument to the contrary confuses [REDACTED] with the rights of a litigant in this Court.

Second, as to Sandoz Inc., that certain of the prior art references new to Sandoz Inc.'s Amended Invalidity Contentions could theoretically have been identified and analyzed by Sandoz Inc. before serving its Preliminary Invalidity Contentions does not demonstrate a lack of diligence. For example, Plaintiffs assert that Sandoz Inc. should have found and appreciated the Savola Thesis available from "six sources" around the world, according to Plaintiffs, by the time Sandoz Inc. served its original contentions. But the database listing for this document, had it been found, does not reveal the suggestion of the claimed invention that lies within. Plaintiffs likewise argue that certain other references should have been cited previously because they were among the more than 100 cited in a review article known to Sandoz Inc. Plaintiffs' assertions, however, do not undermine Sandoz Inc.'s showing that it diligently identified, reviewed and analyzed these prior art references in light of documents being contemporaneously produced by Plaintiffs that shed light on their meaning. [REDACTED]

[REDACTED]

[REDACTED]

Third, and most tellingly, with respect to all but one of the new references, Plaintiffs fail to identify any prejudice. Moreover, Plaintiffs' contention that Talke 1995 will require construction of two additional claim terms falls far short of demonstrating prejudice. Even if the parties cannot agree on constructions for these terms (appearing in a few dependent claims in the '867 Patent), they easily could be briefed on an expedited schedule without risking any significant delay, let alone expiration of the 30-month stay.

ARGUMENT

I. SANDOZ CANADA IS A NEW PARTY TO THE CASE AND HAS THE RIGHT TO SERVE INVALIDITY AND NON-INFRINGEMENT CONTENTIONS, AND TO BE SERVED WITH INFRINGEMENT CONTENTIONS

Due process, at its most basic, requires that parties to an action have a right to mount a defense. In *Nelson v. Adams U.S.A., Inc.*, 529 U.S. 460 (2000), the Supreme Court affirmed this principle and held that adding a third party to a case post-judgment violated due process—even where the third party controlled the corporation already named as a defendant. *Id.* at 468. In *Nelson*, the defendant had obtained an award of attorneys' fees against plaintiff Ohio Cellular Products, a one-person company controlled by the sole proprietor and president Mr. Nelson. *Id.* at 463. The Supreme Court held that though Mr. Nelson was well aware of and intimately involved in the claims brought by his company, the defendant's efforts to add him to the case without allowing him an independent defense deprived him of due process. *Id.* at 468.

Plaintiffs here are seeking a similar result—to preclude Sandoz Canada from litigating its claims and defenses using any invalidity or non-infringement arguments other than those previously asserted by another party. That approach contradicts fundamental considerations of due process, as well as the Local Patent Rules of this Court.

A. The Local Patent Rules Require That Plaintiffs Serve Contentions on New Parties, and That New Parties Serve Contentions in Their Defense

Plaintiffs do not—and cannot—dispute that the Local Patent Rules require that Plaintiffs serve infringement contentions “[s]eparately for each opposing party” (L. Pat. R. 3.1) and that “each party opposing a claim of infringement” serve invalidity contentions (L. Pat. R. 3.3). (Sandoz Br. at 12-13.) Plaintiffs’ suggestion that a later named defendant nevertheless can be “bound” by contentions of another previously served (Pls. Br. at 7-8) is contradicted by these requirements and also by the “Scope and Construction” of the Local Patent Rules. (See L. Pat.

R. 1.2.) As with the Federal Rules of Civil Procedure, the Local Patent Rules must be applied to afford due process. *See Nelson*, 529 U.S. at 465 (“The Federal Rules of Civil Procedure are designed to further the due process of law that the Constitution guarantees.”).

Local Patent Rule 1.2 supports the conclusion that parties added to a case are entitled to their own service of contentions. Local Patent Rule 1.2 explains the application of the Local Patent Rules to amendments that raise claims of patent infringement in a case not already under the Local Patent Rules:

These rules apply to all civil actions filed in or transferred to this Court which allege infringement of a patent in a complaint, counterclaim, cross-claim or third party claim If the filings or actions in a case do not trigger the application of these Local Patent Rules . . . the parties shall, as soon as such circumstances become known, meet and confer for the purpose of agreeing on the application of these Local Patent Rules to the case and promptly report the results of the meet and confer to the Court.

(L. Pat. R. 1.2.) Under this rule, a claim of patent infringement brought, for example, by third party claim later in the case, is not exempt from the Local Patent Rules. Rather, it is expressly covered by them, and the parties must meet and confer to agree on how the rules should be implemented in those circumstances.

Although Local Patent Rule 1.2 does not specifically address the situation where a party is added to a case already covered by the Local Patent Rules, the same logic applies, *i.e.*, the parties should meet and confer to set a schedule under which the parties comply with the rules with respect to the new party. Sandoz Canada sought to do exactly that, and was flatly turned down by Plaintiffs. (Sandoz Br. at 4-6.) Notwithstanding Plaintiffs’ refusal to engage Sandoz Canada in the process contemplated by the Local Patent Rules, Sandoz Canada is entitled to serve contentions in support of its claims and defenses in this action, and it is due contentions from Plaintiffs in response. (*Id.* at 12-15.)

B. Sandoz Canada's [REDACTED] and Corporate Relationship to Sandoz Inc. Does Not Bind Sandoz Canada to Contentions Previously Served by Sandoz Inc.

Plaintiffs wrongly attempt to bind Sandoz Canada to Sandoz Inc.'s previously served contentions by arguing that Sandoz Inc. and Sandoz Canada (1) must have worked together on [REDACTED], (2) "face the same basis for liability in this lawsuit[.]" (3) "are part of the same corporate family[.]" and (4) acted wrongly to gain a tactical advantage in this action by [REDACTED] (Pls. Br. at 1-2, 7, 9.) As demonstrated in Defendants' opening brief and below, Plaintiffs' position is untenable.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2. Plaintiffs' Claims Against Sandoz Inc. and Sandoz Canada Are Not the Same

Nor does Sandoz Canada face "the same basis for liability in this lawsuit" as Sandoz Inc. (Pls. Br. at 2.) Sandoz Canada is based in Boucherville, Quebec, Canada, [REDACTED]

(Ex. 1 at SDZ(8)0000001, 0000008.) Thus, Plaintiffs' allegation that Sandoz Canada will infringe the Patents-In-Suit after FDA approval of Generic Dexmedetomidine, necessarily is one of induced infringement. *See MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1375 (Fed. Cir. 2005) ("It is well-established that the reach of section 271(a) is limited to infringing activities that occur within the United States."). Even for claims as to which both Sandoz Canada and Sandoz Inc. are accused of induced infringement, Plaintiffs' theories of infringement—based on knowledge of the Patents-In-Suit, specific predicate acts of direct infringement, and specific acts that induce those direct infringements—necessarily are separate and distinguishable. *See 14i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010).

Thus, Plaintiffs' faulty premise that Sandoz Canada faces the same basis for liability cannot justify a departure from the reciprocal requirements of the service of contentions by and upon Sandoz Canada under the Local Patent Rules. Indeed, that the bases for liability are different supports the opposite conclusion: Plaintiffs must serve contentions specifically setting forth their allegations of infringement by Sandoz Canada, and Sandoz Canada has the right to serve contentions in defense of Plaintiffs' allegations. (Sandoz Br. at 12-15.)

3. Sandoz Inc.'s and Sandoz Canada's Corporate Relationship Does Not Limit Sandoz Canada's Rights as a Litigant

Plaintiffs conclude that because Sandoz Inc. and Sandoz Canada are part of the same corporate family, Sandoz Canada has no rights in this litigation. But Plaintiffs themselves acknowledged that the positions of the companies are different and distinct when Plaintiffs rejected Sandoz Canada's proposed stipulation to remain out of the litigation and named Sandoz Canada as a separate defendant. (Sandoz Br. at 4-6.) As a separate defendant, Sandoz Canada

has obligations and rights, including the right to due process.¹ *See generally Nelson*, 529 U.S. at 463-68.

Plaintiffs cannot have it both ways. Plaintiffs chose, in suing Sandoz Canada, not to assume the risk that a victory against Sandoz Inc. might not be enforceable against Sandoz Canada. But having obtained the benefit of certainty that a judgment in this case will bind Sandoz Canada, Plaintiffs now refuse to accept the consequence that Sandoz Canada is entitled to serve contentions in its own defense. That result is contrary to fundamental due process. Plaintiffs' decision to exercise their right to sue Sandoz Canada cannot simultaneously deny Sandoz Canada its right to mount a defense.

4. Sandoz Canada's [REDACTED] Was Not Hidden From Plaintiffs

Plaintiffs' contention that Sandoz Canada [REDACTED] [REDACTED] and to gain a tactical advantage under the Local Patent Rules of the District of New Jersey—months before ever being sued in New Jersey—is baseless and illogical. (Pls. Br. at 2-3, 9.) Sandoz Canada's [REDACTED] [REDACTED] (Ex. 1 at SDZ(8)0000001.) [REDACTED] [REDACTED] (Ex. 1 at SDZ(8)0002777-2778.) Thus, Plaintiffs cannot dispute that they knew [REDACTED] as of December 17, 2009, before Sandoz Inc. even served its preliminary invalidity and non-

¹ Plaintiffs' contention that Sandoz Canada's representation by the same counsel as Sandoz Inc. weighs in favor of binding Sandoz Canada to positions previously taken by Sandoz Inc. is a non-starter. (Pls. Br. at 1-2, 7.) The premise that Sandoz Canada's rights are limited based on its choice of counsel contradicts basic principles of due process.

infringement contentions on December 31, 2009. Thus, the supposition that Sandoz Canada's [REDACTED] to allow a second bite at the apple under the Local Patent Rules does not withstand scrutiny.

Finally, Plaintiffs ignore the fact that Sandoz Canada negotiated with Plaintiffs to avoid joinder as a defendant, a negotiation that Plaintiffs terminated. (Sandoz Br. at 4-6.) Plaintiffs chose to add Sandoz Canada as a defendant to this case for their own reasons, and they did so in May 2010, five months after knowing of Sandoz Canada's role. Now, lacking any sound legal basis to support their hope to preclude Sandoz Canada from asserting a defense, Plaintiffs' resort to conspiracy theories provides no recourse.

II. SANDOZ INC.'S AMENDED INVALIDITY AND NON-INFRINGEMENT CONTENTIONS ARE TIMELY AND WILL NOT PREJUDICE PLAINTIFFS

A. Sandoz Inc.'s Amended Invalidity Contentions Supplement the Invalidity Theories in Sandoz Inc.'s Initial Contentions, are Timely, and Will Not Prejudice Plaintiffs

Plaintiffs' strident opposition to Sandoz Inc.'s request to amend its contentions based on documents produced by Plaintiffs and certain additional prior art references merely confirms Plaintiffs' desire to avoid litigating the validity of the Patents-In-Suit in light of this important evidence. But Plaintiffs' claim that these contentions are somehow unfairly game-changing cannot be credited. Sandoz Inc.'s amended contentions largely elaborate on the theories of Sandoz Inc.'s initial contentions based on [REDACTED]. Therefore, and because Plaintiffs fail to rebut Sandoz Inc.'s diligence or demonstrate any unfair prejudice, Sandoz Inc. should be granted leave to serve its Amended Invalidity Contentions.²

² As set forth in Sandoz Canada's and Sandoz Inc.'s opening brief, the contentions of Sandoz Inc. should also be allowed as they mirror the contentions of Sandoz Canada served as of right. (Sandoz Br. at 15-16.) The discussion below shows additionally why Sandoz Inc.'s contentions are proper even
(Footnote continues on next page.)

1. Sandoz Inc.'s Proposed Amendments Further Support its Initial Contentions That the Patents-In-Suit are Invalid

Sandoz Inc.'s initial contentions showed that the '214 Patent, which claimed dexmedetomidine and certain pharmaceutical compositions and methods for its use, was invalid because:

- medetomidine, a well-known sedative, was known to be comprised of two forms, one of which was dexmedetomidine (Ex. 5 at 3-7);
- one form of medetomidine would be more active than the other was expected (*id.*); and
- separation of dexmedetomidine from medetomidine was obvious to try using known techniques (*id.*).

These were exactly the conclusions reached by the PTO. (9/22 Mooney Ex. 1.)

Plaintiffs overcame the PTO's rejections on this ground by pointing to Table 2 of the patent (reproduced below) and arguing that the activity of dexmedetomidine was much better than would be expected and that the "surprising activity" was "particularly noticeable with respect to the α_2 - α_1 -selectivity ratio." (9/22 Mooney Ex. 2 at 3.)

Compound	³ H-clonidine displacement IC ₅₀ , nM	³ H-prazosin displacement IC ₅₀ , nM	α_2/α_1 selectivity
d-enantiomer	1.2	55019	45,849
l-enantiomer	45	189973	4,129
medetomidine	3.3	18700	5,060
detomidine	3.7	242	65
clonidine	6.4	6200	969

Applicants argued to the PTO that based on the selectivity ratios of medetomidine (5,060) and the l-enantiomer (4,129), one of ordinary skill would expect the d-enantiomer to have a α_1 - α_2 -selectivity of about 6,000, *i.e.*, 1.2 times that of the racemate (medetomidine). (*Id.*) Applicants, however, argued that the d-enantiomer showed a selectivity ratio "of 45,849 *i.e.*, more than nine

(Footnote continued from previous page.)
considered on their own.

times that of the racemate [medetomidine]”—a result that was allegedly “completely unexpected and could not be predicted.” (*Id.*)

Sandoz Inc.’s Preliminary Invalidity Contentions showed both the activity and selectivity data reported in the patent—and characterized and relied upon in arguments to the PTO—were demonstrably incorrect. (Ex. 5 at 7-8.) In light of that fact, the alleged “unexpected results” associated with the compound cannot be shown, and the PTO’s initial conclusions of obviousness should stand. (*Id.*) Sandoz Inc.’s amended contentions expand on these points by showing that:

- Prior to filing for the '214 Patent, a doctoral candidate working with Plaintiffs published a thesis expressly suggesting the benefits of separating dexmedetomidine into its constituent enantiomers (*see* Ex. 13 at 5-14; Ex. 14 at ORN-PRECEDEX00018144);

- [REDACTED]

- [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED]	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED]	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]

Sandoz Inc.'s initial contentions as to the '867 Patent similarly show that the uses of dexmedetomidine claimed in that patent would have been obvious. (Ex. 5 at 11-22.) Sandoz Inc.'s initial contentions show that dexmedetomidine was known to be similar to clonidine, and that the use of both in perioperative settings (before, during, and after surgery) to achieve variable states of sedation was also well known. (*Id.*) Sandoz Inc.'s amended contentions supplement this analysis, primarily based on citations to articles by Dr. Talke, in 1995 and 1997, who reported on studies funded by Plaintiffs. (*See* Ex. 13 at 20-43; Ex. 19; Ex. 20.) Those studies addressed what the prior art cited originally by Sandoz Inc. made clear—that particular

sedative effects of dexmedetomidine could be achieved in a clinical intensive care setting, and that particular dosages could be determined to achieve those effects. (*Id.*)

2. Plaintiffs' Speculative Arguments that Sandoz Inc. Should Have More Promptly Reviewed Plaintiffs' Documents and Uncovered Prior Art Do Not Withstand Scrutiny

Plaintiffs' arguments of lack of diligence ring hollow, especially given that Plaintiffs are arguing that Sandoz Inc. should be precluded from presenting evidence of invalidity based on

[REDACTED]

[REDACTED]

[REDACTED], their arguments that Sandoz Inc. was not diligent are flawed in several respects.

According to Plaintiffs, the

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As such, they are not easy to identify, and it is not at all clear that such documents need be cited in contentions under the Local Patent Rules.⁴ And, these documents were produced in February among approximately 500,000 pages of documents. (Sandoz Br. at 19-20.) In view of the fact that the import of such documents is not immediately apparent, and that they were produced among half-a-million pages of unsearchable text,

[REDACTED]

[REDACTED]

Plaintiffs have no cause to complain of lack of diligence in reviewing Plaintiffs' production, identifying these references, and analyzing their relevance to Sandoz Inc.'s claims and defenses. (*Id.* at 8-10, 19-21.)

The claim that Sandoz Inc. should previously have identified the Savola Thesis, written 24 years ago by Savola while attending a Finnish university, also fails. (Pls. Br. at 14.)⁵ The mere fact that "the title and abstract of the Savola Thesis is included in [the] Dialog [database]", or is available from "six sources" around the world, does not undermine Sandoz Inc.'s diligence in uncovering and analyzing the reference—especially given that neither the title nor the abstract even mentions the evaluation of the enantiomers of medetomidine. (Ex. 14.) From the database entry, Sandoz Inc. could not have ascertained that the thesis discloses more than medetomidine, which was already admitted prior art to the '214 Patent. Plaintiffs' position is tantamount to arguing that all published prior art cognizable under § 102 must be identified by a litigant. That is not the law. *See* L. Pat. R. 3.7 (allowing amendments to invalidity contentions).

The assertion that Sandoz Inc. should have identified and appreciated the relevance of Talke 1995 by December 2009 because it was cited in Aantaa 2006 also is baseless. (Pls. Br. at 10.) Aantaa 2006 cites almost 120 different articles. (9/22 Mooney Ex. 3.) Plaintiffs, on the other hand, have long been aware of the work reported in this article and funded by them more than 15 years ago. (Sandoz Br. at 11.) Finally, while Sandoz Inc. was aware of Talke 1995 by April 2010, as Plaintiffs contend, Sandoz Inc. continued to analyze and develop its invalidity positions in the following months and thereafter prepared to follow an agreed schedule for contentions after Sandoz Canada appeared in the action. (*Id.* at 20-21.) Sandoz Inc. was diligent

⁵ Sandoz Inc. inadvertently characterized the Savola Thesis "confidential" at page 10 of its opening brief. The Savola Thesis, however, was not designated as "confidential" by Plaintiffs under the Discovery Confidentiality Order. (Ex. 14.)

in its investigation and promptly provided Plaintiffs with its amended contentions when they rejected efforts to work out a schedule for the service of contentions by Sandoz Canada. (*Id.* at 4-5, 21.)

Sandoz Inc. was likewise diligent in its identification of the other references of which Plaintiffs' complain.⁶ Although Aho is cited in Aantaa 2006 (Pls. Br. at 12.), along with almost 120 other references, neither the citation to Aho nor the title of the article make clear the specific potential relevance of the reference to the claims of the '867 Patent. (*See* 9/22 Mooney Ex. 3.) Likewise, although Wilffert, Dabiré 1985 and Easson are cited in Savola 1991 (Pls. Br. at 13.), the mere identification of those references does not make clear their specific potential relevance of the references to the claims of the '214 Patent. (*See* 9/22 Mooney Ex. 4.) Further, Plaintiffs' bald assertion that Talke 1997, Dabiré 1986, Welbourne and Filos "could have been found by reasonably diligent searches" (Pls. Br. at 12, 13) does not undermine Sandoz Inc.'s showing of diligence in identifying and analyzing these references and their relationship to the confidential information recently produced by Plaintiffs in this action. (*See* Sandoz Br. at 19-21.)

Finally, contrary to Plaintiffs' suggestion (Pls. Br. at 15.), Sandoz Inc.'s Section 112 argument for the '214 Patent was included in its original contentions and has not been substantially revised. (*Compare* Ex. 5 at 9 with Ex. 13 at 16-17.) Rather, the amended contentions merely drop an argument no longer being pursued by Sandoz Inc., and add a citation to the Federal Circuit's decision in *Ariad Pharmaceuticals, Inc. v. Ely Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*)—decided in March 2010 after Sandoz Inc. served its initial contentions. Sandoz Inc.'s Section 112 arguments for the '867 Patent (Pls. Br. at 12.)

⁶ Contrary to Plaintiffs' suggestion (Pls. Br. at 13), Aantaa 2006, Scheinin 1987b and Virtanen 1988 all were identified in Sandoz Inc.'s Preliminary Invalidity Contentions and are not new to Sandoz Inc.'s Amended Invalidity Contentions. (Ex. 5 at 3, 7-8, 11.)

likewise have been revised based on internal documents produced by Plaintiffs after Sandoz Inc.'s original contentions were served, and to extend the "effective amount" argument made for the '214 Patent to the '867 Patent. (*Compare* Ex. 5 at 22-23 with Ex. 13 at 43-44.)⁷

3. Plaintiffs' Argument That They Will Be Unfairly Prejudiced by Sandoz Inc.'s Amended Invalidity Contentions is Baseless

Plaintiffs fail to identify any alleged unfair prejudice with respect to any references or documents identified in Sandoz Inc.'s Amended Invalidity Contentions other than Talke 1995. (Pls. Br. at 17-18.) Thus, the Court should grant Sandoz Inc.'s motion with respect to each and every one of those references and documents. (Sandoz Br. at 17-24.)

The Court also should grant Sandoz Inc.'s motion with respect to Talke 1995. The sole prejudice that Plaintiffs identify is that the inclusion of Talke 1995 in Sandoz Inc.'s Amended Invalidity Contentions requires construction of two terms that appear in certain dependent claims of the '867 Patent, *i.e.*, "loading dose" and "maintenance dose." (Pls. Br. at 17-18.) Plaintiffs speculate that they will be prejudiced because this will delay resolution of claim construction until after expert discovery and will allegedly risk postponing the trial beyond expiration of the 30-month stay. (Pls. Br. at 17-18.) Plaintiffs' claim of unfair prejudice is unfounded.

As an initial matter, Plaintiffs' suggestion that Sandoz Inc. somehow misled Plaintiffs to their detriment by dropping "maintenance dose" and "loading dose" from the terms to be construed despite knowledge of Talke 1995 is contradicted by the record. (Pls. Br. at 10, 17-18.)

██

██

⁷ Sandoz Inc. also added Section 112 arguments based on the failure to recite an amount of composition or active ingredient (Claim 3), and that Claim 4 is broader in scope than Claim 1 from which it depends—both consistent with the contentions recently served by Sandoz Canada. (Ex. 13 at 45.)

[REDACTED] Nevertheless,

Moreover, the Court has not yet scheduled a Markman hearing, let alone ruled on claim construction. The parties may be able to agree on the construction of these terms and, if not, these terms could be simply and efficiently briefed within a few weeks.⁸ Significantly, however, the terms are not so complex that if a claim construction ruling is not issued before expert discovery commences, the parties' experts could easily take the different positions into account. Ultimately, there is not any reasonable risk that the construction of these straightforward terms in dependent claims will risk completing this trial before the 30-month stay expires.⁹

B. Sandoz Inc.'s Amended Non-Infringement Contentions are Based on Dr. Ramsay's Recent Testimony and Will Not Unfairly Prejudice Plaintiffs

Plaintiffs argue that Sandoz Inc. lacks good cause for amending its non-infringement contentions because Dr. Ramsay's recent testimony was allegedly cumulative of the Precedex® label. (Pls. Br. at 15-16.) Plaintiffs, however, do not even attempt to identify on the Precedex®

⁸ Significantly, had Plaintiffs identified these limitations when they informed the Court that the new prior art implicated some additional claim construction issues more than one month ago, the parties might already have agreed on a construction or briefed any disputes. (Sandoz Br. at 23 n.18.) Instead, Plaintiffs have focused on keeping material prior art out of the case, rather than on efficiently litigating the merits of this dispute. (See generally *id.* at 3-7.)

⁹ Plaintiffs assert that neither Sandoz Canada nor Sandoz Inc. should be able to serve contentions because “counsel representing Sandoz Canada told this Court in May that they could ‘ensure that disclosures can be made and claim construction briefing completed by August 6, 2010.’” (Pls. Br. at 17.) Plaintiffs ignore that, after waiving its defense of personal jurisdiction and joining issue (which did not happen until July 1, 2010), Sandoz Canada did promptly reach out to Plaintiffs on scheduling issues, and that Plaintiffs rejected Sandoz Canada’s efforts and ran to the Court. (Sandoz Br. at 5-8.) And, as set forth above, Plaintiffs’ claim of prejudice based on the alleged need to construe two claim terms because of a single reference (Talke 1995) fails, as those terms could easily be addressed on the merits in the time Plaintiffs have taken to oppose on procedural grounds.

label all of the information that [REDACTED]. The Precedex® label, for example, merely provides that the drug should be titrated to an undefined “desired clinical effect” or “desired level of sedation,” states that some patients have been observed to be “arousable and alert,” and describes trials where the drug was titrated to a Ramsay Sedation Score of 3 or more. (9/22 Mooney Ex. 5 at 4-6.) The label does not discuss whether all patients treated with the recommended doses would be sedated in the manner required by the disputed claims.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Further, Plaintiffs’ conclusory assertion that Sandoz Inc.’s new non-infringement argument is “futile” does not amount to a showing of unfair prejudice. (Pls. Br. at 16.) The courts have long demonstrated a preference for resolving infringement disputes on the merits (Sandoz Br. at 24), and the merits of Sandoz Inc.’s non-infringement argument should be fairly litigated on a fully developed record after fact and expert discovery are completed. Moreover, Plaintiffs cannot credibly contend both that the merits of Sandoz Inc.’s non-infringement argument can be fully and fairly resolved by the Court now based on a conclusory paragraph in

Plaintiffs' brief and, at the same time, that Plaintiffs will be substantially and unfairly prejudiced if they are forced to address Sandoz Inc.'s argument on a developed record later in this action.

Finally, Plaintiffs' claim of prejudice also is belied by the fact that Sandoz Inc.'s non-infringement argument is closely related to Sandoz Inc.'s previously articulated positions. Sandoz Inc. told Plaintiffs, in both its Preliminary Non-Infringement Contentions and its claim construction briefing, that several claims of the Patents-In-Suit are not infringed because the administration of Generic Dexmedetomidine in the ICU approved dosages is not administration of the required "effective amount." (Ex. 6 at 3-4; D.I. 83 at 1.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Sandoz Inc.'s non-infringement defenses, therefore, are closely related and both concern the claimed method of use (not composition) of Generic Dexmedetomidine. (See Ex. 6; Ex. 12.)

C. The Scope and Timing of Sandoz Inc.'s Amendments are Consistent With Those Allowed by This and Other Courts

As discussed above, Sandoz Inc.'s amendments are important, expand on theories made from the outset of this case with information diligently identified and analyzed, have been made at the midpoint of the case and well before the close of discovery or a Markman decision, and will not prejudice Plaintiffs. As demonstrated in Sandoz Inc.'s opening brief, the relevant case law supports granting Sandoz Inc.'s motion to amend. (Sandoz Br. at 15-24.)

For example, in *Golden Hour Data Systems, Inc. v. Health Services Integration, Inc.*, the court granted defendant's motion for leave to amend invalidity contentions based on the following considerations:

- the “amendments do not raise new issues but instead merely supplement [the] initial contentions” and the plaintiff, therefore, “was already on notice regarding the substance of [the] proposed amendments”;
- the amendments were based on important prior art uncovered during discovery in the litigation;
- the amendments “do not leave [Plaintiff] with little time to conduct discovery, as an additional three months remain in the fact discovery period” and trial was nine months away;
- expert discovery had not yet begun and “[Plaintiff’s] experts will have the opportunity to consider the amended contentions.”

No. 06-7477, 2008 U.S. Dist. LEXIS 75495, at *13-14 (N.D. Cal. July 1, 2008). Each of these factors is present in this case. Critically, *Golden Hour* emphasizes the focus on a plaintiff’s notice of the documents and invalidity theory, and whether a plaintiff actually would be prejudiced by the amendment. *See id.*

Avago Technologies General IP PTE Ltd. v. Elan Microelectronics Corp. also demonstrates the focus on notice and prejudice factors in the analysis. In *Avago*, the court granted the defendant’s motion to amend invalidity contentions eight months after the claim construction hearing, and after the defendant questioned the plaintiff’s expert and filed a summary judgment motion based on the theory. No. C04-05385, 2007 U.S. Dist. LEXIS 39543, at *2-3, 5-7 (N.D. Cal. May 15, 2007). The court determined that Plaintiff “will not be significantly prejudiced” because it “will have known about this theory for almost three months before its opposition of the relevant summary judgment motion is due” and “all of the documents that this theory is based on have been in [Plaintiffs’] possession for at least as long as they have been in [Defendant’s].” *Id.* at *6.

Likewise, in *Lexar Media, Inc. v. Pretec Electronics Corp.*, the court granted the defendant’s motion to amend invalidity contentions, after fact discovery closed, to include a theory previously disclosed in claim construction, but not made part of amended contentions

until years later. No. 00-04770, 2007 U.S. Dist LEXIS 32825, *2-3 (N.D. Cal. Apr. 18, 2007).

The court found that “Plaintiff was . . . on notice of these allegations” and to preclude them “would elevate form over substance” given that no particularized showing of prejudice could be made. *Id.*

The recent decisions of this Court are in accord. In *TFH Publications v. Doskocil Manufacturing Co.*, a short but unexplained delay in amending infringement contentions was permitted, even though it would require responsive invalidity contentions to be revised, where the proposed amendments would “not significantly delay the resolution of [the] matter.” No. 08-4805, 2010 U.S. Dist. LEXIS 33611, at *12-13 (D.N.J. Apr. 6, 2010). Conversely, in *King Pharmaceuticals, Inc. v. Sandoz Inc.*, No. 08-5974, 2010 U.S. Dist. LEXIS 50163 (D.N.J. May 20, 2010), the Court declined to allow certain amendments on facts that suggested a substantial risk of prejudice. In *King Pharmaceuticals*, the defendant had identified the new prior art reference 18 months before moving to amend, the claim construction ruling had issued, trial was just a few months away, and plaintiffs had planned a litigation strategy that did not account for the new prior art (of which there is no indication they had any prior notice). *Id.* at *11-14. In denying the motion and despite diligence arguments that were “not compelling”, the court focused on whether the plaintiffs actually would be unfairly prejudiced by the amendment. *Id.* at *12-13.

Likewise, in *CBS Interactive, Inc. v. Etilize, Inc.*, relied upon by Plaintiffs, the District Court for the Northern District of California denied the defendant’s motion to amend invalidity contentions where defendants failed to explain their delay in moving to amend, and plaintiff would have been substantially and unfairly prejudiced by an “eleventh hour” revision of

defendant's theories—fact and expert discovery had closed, and defendant's dispositive motion on invalidity had been fully briefed. 257 F.R.D. 195, 200-03 (N.D. Cal. 2009).¹⁰

Here, the facts are much closer to *Golden Hour*, *Avago*, *Lexar Media*, and *TFH* than they are to *King Pharmaceuticals* or *CBS Interactive*. The key prior art references [REDACTED] were long known to Plaintiffs, they simply corroborate and bolster invalidity theories already set forth in Sandoz Inc.'s original contentions, [REDACTED]

[REDACTED] Critically, as in *Golden Hour*, *Avago*, *Lexar Media*, and *TFH*, Plaintiffs will not suffer any actual unfair prejudice by the amendments: the claim construction order has not issued, four months remain in fact discovery, about one year remains before trial, and the 30-month stay does not expire for another 16 months. (Sandoz Br. at 21-24.)

CONCLUSION

For the foregoing reasons, Sandoz Canada respectfully requests that the Court order that Sandoz Canada's Preliminary Invalidity and Non-Infringement Contentions were properly served and order Plaintiffs to serve Infringement Contentions addressing Sandoz Canada's alleged infringement; and Sandoz Inc. respectfully requests that the Court grant it leave to serve Amended Invalidity Contentions and Amended Non-Infringement Contentions.

¹⁰ Plaintiffs' reliance on *O2 Micro International Ltd. v. Monolithic Power Systems, Inc.*, 467 F.3d 1355 (Fed. Cir. 2006) is likewise misplaced. (Pls. Br. at 5-6.) In *O2 Micro*, the Federal Circuit reaffirmed that district courts are vested with broad discretion to rule on amendments, and affirmed denial of a motion to amend where plaintiff had reason to know of the new infringement theories 15 months before moving to amend, and moved to amend only after the close of fact discovery and with only a few weeks left in expert discovery. *Id.* at 1366-67. By contrast, Sandoz Inc. has not unduly delayed, fact discovery does not close for four months, and expert discovery does not begin for about five months.

Dated: September 22, 2010

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CERTIFICATE OF SERVICE

I, CHRISTINA SAVERIANO hereby certify that I caused a copy of SANDOZ CANADA AND SANDOZ INC.'S MEMORANDUM OF LAW IN RESPONSE TO PLAINTIFFS' REQUEST TO PRECLUDE SANDOZ INC.'S AND SANDOZ CANADA INC.'S PROPOSED INVALIDITY AND NON-INFRINGEMENT CONTENTIONS to be served via e-mail on the following counsel on September 22, 2010:

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